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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

7590

06/24/2003

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,243

Applicant(s)

PARIKH ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Response, and the Resubmission of pages 4 and 5 of an earlier filed Information Disclosure Statement, both received by the Office April 14, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2-53271 to Okada *et al.* in view of US Patent 4,309,405 to Guley *et al.*. [All page citations for Okada *et al.* refer to Applicant's provided translation.] Okada *et al.* disclose a tablet containing coated granules characterized in that the coated granules are further coated by a protective film of water-soluble polymer or of acid-soluble polymer (claim 1). Okada *et al.* teach that it is widely known in the art to use enteric, acid soluble, or insoluble films to coat granules to hide taste or odor and to add various functions such as sustained release (p 2, para 4). The film of the coated particles is comprised of one or two or more of enteric polymers or wax (claim 2). There is an active medicinal drug product contained in the coated granules (claim 3). Additionally, Okada *et al.* teach that the protective film can be one of the following, or a mixture of two or more, including HPMC, HPC, MC, PVP, PEG and gelatin (p 2, para 7).

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Okada *et al.* do not teach examples of the enteric and insoluble polymers used in the first coating layer.

Guley *et al.* teaches sustained release pharmaceutical compositions. However, the Guley *et al.* reference is relied upon for the teaching of specific insoluble and enteric coating polymers. Guley *et al.* teaches that ethylcellulose is a well known insoluble polymer used in pharmaceutical compositions (c 2, l 45-49). Additionally, Guley *et al.* teaches that well known enteric coating materials include cellulose acetate phthalate, and HPMC phthalate (c 3, l 15-20).

To summarize, Okada *et al.* teach a granule coated with an enteric or insoluble polymer, and then further coated with a polymer or mixture of polymers to prevent breakage. Okada *et al.* suggests the combination of HPMC and PEG as the outer film protective coating. Okada *et al.* does not specify polymers useful in the first coating layer. Guley *et al.* teaches well known enteric and insoluble polymers, for use in coating pharmaceutical compositions. It is the position of the examiner that one of ordinary skill in the art would have been motivated to look to teachings in the art to provide examples of well known insoluble polymers and enteric coating polymers. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any of the insoluble polymers discussed by Guley, and any of the enteric polymers disclosed by Guley, in the first coating layer disclosed by JP '721, because JP '721 requires the specific types of coatings, but does not give specific examples. The expected result in using one of the polymers specified in Guley as the first coating on the granules discussed in Okada *et al.* would be a successfully coated granule with taste masking, odor masking, or other functional capabilities which aid in sustained release (Okada *et al.*, p 2,

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para 4). For these reasons, the invention of applicant would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed April 14, 2003 have been fully considered but they are not found to be persuasive. Applicant argues that Guley is silent regarding suitable coatings for particles. More specifically, Applicant argues that Guley discusses coatings for core tablets, rather than individual particles which can be combined with other particles to form a tablet core. The examiner finds this argument to be unpersuasive. As stated in the above rejection, the Guley reference is relied upon for the teaching of specific insoluble and enteric coating polymers. It is the position of the examiner that the fact that Guley is coating tablet cores rather than particles makes no difference. Guley was relied upon to give specific examples of the generic type of coating taught by Okada *et al.*. A teaching regarding well known enteric polymers and which of these polymers are known in the art should not be held non-analogous merely because the formulation being coated in the reference is a tablet core rather than a particle. For these reasons, the above rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
June 17, 2003


THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
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